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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,513	03/26/2001	Therese Jourdiar	MBHB00-1282	3546

20306 7590 07/29/2003

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CHICAGO, IL 60606

EXAMINER
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LI, BAO Q

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/29/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/720,513

Applicant(s)

JOURDIER ET AL.

Examiner

Bao Qun Li

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

### **DETAILED ACTION**

Claims 10-15 are pending.

#### ***Response to Amendment***

This is a response to the amendment, paper No. 13, filed 05/12/03. Claim 10 has been amended. Claims 10-15 are pending and considered before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

#### ***Claim Rejections - 35 USC §103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 10-15 are rejected under 35 U.S.C. 102(a) on the same ground as stated in the previous Office Action as being unpatentable over Carrano et al. (WO 95/26718A1), Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403), Stites et al. (Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut) and Bouvet et al. (Infect. Immun. 1994, Vol. 62, pp. 3957-3961).

3. Applicants argue that the claimed invention is an unexpected property of injecting an immunogene at the thigh of an pathogen is able to induce an systemic as well as a local immune response of IgA, IgG or IgM or B cells secreting said antibodies that are targeted at the recotogenitourinary mucous membrane and the lymph node which drain it. No reference has taught that method and this mechanism either.

4. Applicants' argument has been respectfully considered; however, it is not found persuasive because the method of injecting a pathogen into the thigh area is known in the art. For example, both Groswasser et al. (Pediatrics 1997, Vol. 100, page 400-403) and Stites et al.

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(Medical Immunology edited by Stites et al. 1997, pages 782, Appleton & Lange, Stamford, Connecticut). Stities et al. teach to use thigh area for the immunization. In particular, Groswasser et al. disclose that a better immune response for intramuscular compared with subcutaneous injection has been seen with several vaccines, such as the hepatitis B, rabies and influenza vaccines (See first paragraph on page 400), wherein the thigh injection referred by Dr. Groswasser et al. is the site of quadriceps (See section of materials and methods on page 401). Whereas, the limitation of “inducing an systemic as well as a local immune response of IgA, IgG or IgM or B cells secreting said antibodies that are targeted at the recotogenitourinary mucous membrane and the lymph node which drain it” is to elaborate the mechanism of the method, which function as a preamble language recited in the claims does not result in a manipulative difference in the method steps when compared to the prior art disclosure.

5. Nevertheless, Bouvet et al. teach this limitation by demonstrating that the systematic vaccination can be efficient at the genital level and thus could reinforce or even replace a local vaccine and concluded that systemic-derived immunity in human genital secretions reinforces the potential interest in vaccines given by the parenteral rout in prevention of sexually transmitted diseases because they have showed that an intramuscularly immunization can locally induce for a long period of time a high levels of antibodies, which might be protective against the corresponding pathogen, given the efficacy of the injection antigen. They further teach that the possible of inducing protective antibodies by current procedures before development of true secreting vaccine seems to be of major interest because the antibodies in secretions can play a key role against the pathogens, which remain in the genital area, by increasing their clearance with mucus and by inhibiting their attachment to the mucus. These antibodies could thus decrease, or even suppress, the entry of pathogens through the mucus and avoid overloading of the systemic defenses. Such mechanisms could be useful against sexual transmission of HIV by preventing the virus from reaching the systemic immune system (Se section of Discussion on pages 3959-3960).

6. Therefore, the cited references not only teach each and every limitation of the claimed invention, but also provide a strong motivation for the person with ordinary skill in the art to use the claimed method of thigh injection for inducing a high levels of long-lasting antibodies, which might be protective against the corresponding pathogen in the genital area as suggested.

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Therefore, there is no unexpected result for injecting a pathogen of a sexual transmitted disease at thigh to induce a better protective immune response at local congenital area without unexpected result.

7. Therefore, the rejection is maintained.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

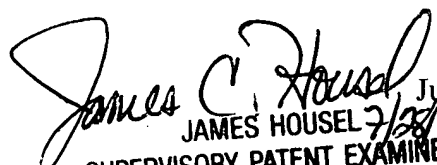
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 703-305-1695. The examiner can normally be reached on 7:00 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bao Qun Li

  
JAMES HOUSEL 7/21/03  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
July 21, 2003